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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,266	06/28/2000	Rama Akella	SBI-066	6018

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HOUSTON, TX 77042

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/605,266

Applicant(s)

AKELLA ET AL.

Examiner

Janet L. Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 18-23, 26, 28, 29, 33-36, 39 and 40 is/are allowed.
- 6) ☒ Claim(s) 9-17, 24, 27, 30-32, 37, 38, and 41-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 December 2004 has been entered. Claims 1-24 and 26-64 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Rejection/Objection Withdrawn***

The rejection of claims 1-5, 7-17, 24, and 27-29 under 35 U.S.C., second paragraph, as indefinite in the recitation of "bone protein mixture" is withdrawn in response to Applicant's amendment.

The objection to claim 28 is withdrawn in response to Applicant's amendment.

The objection to the drawings is withdrawn in response to Applicant's amendment.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38, 46, 54, and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compositions of figures 1-4, does not reasonably

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provide enablement for those of figures 5-6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The artisan would not be able to identify the staining patterns of figures 5 or 6; no staining pattern is identifiable in these figures.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37 and 41-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37, 45, 53, and 61 are indefinite in the recitation of “selected proteins”. The selected proteins are not identified and the artisan would be unable to determine what they are. Thus the artisan would not be able to determine what compositions Applicant intended the claims to encompass.

Claims 41-64 are indefinite because they are method claims that depend from composition claims. For the purposes of examination they are interpreted as encompassing methods of promoting the healing of skin wounds.

### ***Claim Rejections - 35 USC § 102***

Claims 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patents 5,290,763, 5,371,191, and 5,563,124. By Applicant’s own admission on p. 5, lines 4-6 and 27-29, the cocktail instantly claimed is that of these patents. That Applicant has identified certain constituents of the cocktail does not render the cocktail newly patentable. The constituents are

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inherent in the composition, regardless of whether their presence was recognized at the time the cocktail was derived.

Claims 9-17 and 27 are rejected under 35 U.S.C. 103(a) as unpatentable over the '763, '191, and '124 patents.

The '763, '191, and '124 patents teach as set forth above but fail to teach further purification. However, it would have been *prima facie* obvious for the artisan of ordinary skill to undertake such purification. The artisan would have been motivated to do so for purposes of characterization of the mixture, to increase the specific activity of the mixture, and to reduce the formation of aggregates.

Claim 24 is rejected under 35 U.S.C. 103(a) as unpatentable over the '763, '191, and '124 patents and further in view of U.S. patent 5,935,978.

The '763, '191, and '124 patents teach as set forth above but fail to teach the use of anti-inflammatory molecules such as TNF- $\alpha$  inhibitors. The '978 patent teaches TNF- $\alpha$  inhibitors in column 1, lines 16-18 and teaches in column 1, lines 59-63, that they also affect IL-1 and IL-6. The '978 patent teaches that these inhibitors are useful for the prevention of bone resorption and joint inflammation in column 78, lines 25-52. It would be *prima facie* obvious to the artisan of ordinary skill to combine the teachings of the '763, '191, or '124 patents with those of the '978 patent to produce a combination of the bone protein mixture and a TNF- $\alpha$ , IL-1, or IL-6 inhibitor. The artisan of ordinary skill would have been motivated to do so because the two compositions are useful for the same purpose, that is, bone maintenance.

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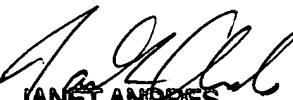
CLAIMS 1-8, 18-23, 26, 28, 29, 33-36, 39, AND 40 ARE ALLOWED. CLAIMS 9-17, 24, 27, 30-32, 37, 38, AND 41-64 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
18 March 2005

  
JANET ANDRES  
PRIMARY EXAMINER